

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 11-651V

July 26, 2013

Not to be Published

PERLA SANCHEZ, Natural Mother
and Administrator for the Estate of the
deceased infant, ERASMO BARRON,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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SIDS; petitioner moves
for dismissal

Thomas P. Gallagher, Somers Point, NJ, for petitioner.
Althea W. Davis, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

On October 7, 2011, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa–10-34, alleging that hepatitis B, diphtheria-tetanus-acellular pertussis (DTaP), haemophilus B influenza (HiB), pneumococcal (Prevnar), inactivated polio

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioner has 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

(IPV), and rotavirus vaccines administered on November 3, 2009 caused the death of her son Erasmo Barron (hereinafter Erasmo) a day later. The petition states the cause was vaccination, without naming a particular condition the vaccines allegedly caused. It does mention that the pathologist who performed the autopsy, Dr. Norma Jean Farley, M.D., identified the cause of death as sudden infant death syndrome (SIDS). Petition, ¶¶ 12, 13.

On May 18, 2013, petitioner filed an amended petition, alleging both causation in fact from the vaccines (Count I), and a “table injury and/or death” (Count II, ¶ 2). Petitioner does not specify what Table injury she alleges. Presumably, she alleges a Table encephalopathy, which requires a significantly decreased level of consciousness. 42 C.F.R. § 100.3(b)(2)(a). A significantly decreased level of consciousness is defined as decreased or absent response to environment, decreased or absent eye contact, or inconsistent or absent responses to external stimuli. 42 C.F.R. § 100.3(b)(2)(D)(1), (2), and (3). There is no evidence in the medical records or petitioner’s affidavits that Erasmo had a significantly decreased level of consciousness. The records and affidavits reflect that Erasmo was doing fine and was not sick or feverish the night before he died. In addition, death is not a Table injury. Hellebrand v. Sec’y of HHS, 999 F.2d 1565 (Fed. Cir. 1993).

On July 10, 2013, petitioner moved for a ruling on the record, stating that petitioner’s counsel’s “efforts to find an expert to support the client’s position failed.” Pet. Mot., at 2 ¶ 4.

The undersigned **GRANTS** petitioner’s motion for a ruling on the record and dismisses this case.

FACTS

Erasmo was born on September 3, 2009.

On November 3, 2009, at two months of age, he received hepatitis B, DTaP, HiB, Prevnar, IPV, and rotavirus vaccines. Med. recs. Ex. 4, at 36.

On November 4, 2009, Erasmo was found unresponsive. A Pharr Police Department report by Officer Jose A. Luengo states that Erasmo’s mother said Erasmo was doing fine the prior night, and was not sick or feverish. Med. recs. Ex. 6, at 4. She told the officer that she put Erasmo to sleep on the same bed as his brother and two sisters, ages three, four and five. Id. She woke at 3:00 a.m. to check and found him in good health and breathing. Id. She woke at 6:50 a.m. to get the older child ready for school and discovered Erasmo unresponsive. Id. Petitioner wrote in an affidavit dated November 11, 2009 that Erasmo drank only one ounce from the bottle she prepared for him at 3:00 a.m. on November 4, 2009. Id. at 14.

During an interview on November 4, 2009, Officer Luengo spoke with petitioner about the events of November 3, 2009, when Erasmo went to his pediatrician. Petitioner told Officer Luengo that between 6:50 to 8:00 a.m. on November 3, 2009, she fed Erasmo only one ounce of

formula in the morning because he fell back to sleep. Med. recs. Ex. 9A, at 7-8. Erasmo was asleep in the car seat and stayed asleep until they reached the pediatrician's office at 10:00 a.m. when he woke and drank four ounces of formula. Id. Erasmo was awake for about 30 minutes when he received his vaccinations. Id. Between 1:00 and 2:30 p.m., Erasmo drank four more ounces of formula. Id. Between 2:30 and 3:30 p.m., the family arrived home and Erasmo was asleep. Id.

On November 4, 2009, Dr. Norma Jean Farley performed an autopsy. Med. recs. Ex. 6, at 9. Erasmo was found face up in a twin bed, with pillows and blankets, where his three siblings, aged three to five years, were also sleeping. Id. at 12. After examining Erasmo's tissues, Dr. Farley concluded that he died of sudden unexpected infant death or SIDS. The autopsy, toxicology, cultures, and microscopic sections failed to reveal a cause of death. Because he was co-sleeping with three siblings in a twin bed with pillows and blankets, Dr. Farley stated, "This manner of death, in my opinion, is best classified as undetermined since external factors such as accidental overlay or smo[ther]ing in the bed cannot be excluded." Id. at 13.

On November 4, 2009, Special Investigator Javier Gallegos received a call from Dr. Farley's office. Dr. Farley discovered that Erasmo had a functional heart murmur. Med. recs. Ex. 9A, at 11. This was a small functional heart murmur. Id. at 18.

EXPERTS

On March 26, 2012, petitioner filed the expert report of Dr. John Shane, a pathologist, as Exhibit 11. Dr. Shane opines that his viewing of the photographs of the autopsy showed profound flattening of the gyri and narrowing of the sulci of the brain, and cerebral edema and pulmonary congestion. Pet. Ex. 11, at 4. On microscopic examination, Dr. Shane found significant pulmonary congestion and profound pulmonary edema, a spongiotic brain, neuronal degeneration in the brain, and kidney congestion consistent with encephalopathic cardiovascular collapse. Id. He concluded that Erasmo died from a vaccine-related neuropathic process. Id.

On September 21, 2012, respondent filed the expert reports of Dr. Sara O. Vargas, a pediatric pathologist, as Exhibit A, and of Dr. Hart G.W. Lidov, a pediatric neurologist and neuropathologist, as Exhibit C. (On September 27, 2012, respondent moved to strike the former Exhibit C and file a corrected Exhibit C, which motion the undersigned granted in an Order dated September 28, 2012. Citations to Exhibit C will be to the corrected Exhibit C.)

Dr. Vargas states that Erasmo had mild disease of the respiratory tract preceding and at the time of his death. Resp. Ex. A, at 5. These findings would be very unlikely to have caused his death. Id. The heavy weight of Erasmo's lungs is consistent with his lung disease. Id. at 6. Dr. Vargas agreed with Dr. Farley, who did the autopsy, that accidental fatal overlay or smothering was a possible cause of Erasmo's death since he was sleeping with three siblings. Id. She agreed with Dr. Farley's conclusion that this was a case of SIDS. Id. She disagreed with

petitioner's expert Dr. Shane's assessment that Erasmo's brain showed edema and microscopic evidence of a neuropathic process. Id. at 7. Erasmo's brain weighed well within the expected range for an infant of his age. Id. She also disagreed with Dr. Shane that Erasmo's brain showed gross flattening of the gyri and narrowing of the sulci, which was not apparent to either Dr. Farley, who did the autopsy, or to Dr. Vargas. Id. Dr. Vargas did not see any brain abnormalities microscopically on the autopsy slides. Id. Dr. Vargas disagreed with Dr. Shane's opinion that Erasmo had profound pulmonary edema in the lung. Id. at 8.

Dr. Lidov states that Erasmo's fontanel was patently sunken. If he had had cerebral edema, as Dr. Shane reported, the fontanel would be tense or bulging, even in death. Resp. Ex. 3, at 2. Erasmo's sulci were not compressed and the gyri were not flattened, in contradistinction to Dr. Shane's report. Id. Dr. Lidov states he disagrees with every one of Dr. Shane's bases for his opinion. Id. at 3. There was no clinical indication that Erasmo was unwell after his vaccinations and his drinking one ounce of formula is not evidence of encephalopathy. Id. at 4. Erasmo's brain weight was completely normal. Id. Erasmo's Purkinje cells were not degenerated. Id. at 5. Encephalopathic cardiovascular collapse is not a recognized disease process. Id. Erasmo had a minor upper respiratory infection that was far from sufficient to cause his death. Id.

During a telephonic status conference on September 27, 2012, petitioner's counsel agreed that respondent's experts' CVs were more impressive than petitioner's expert Dr. Shane's CV. Petitioner's counsel sought an expert report from a pediatric neurologist to counter respondent's expert Dr. Lidov, who is a pediatric neurologist as well as a pathologist.

During a telephonic status conference on January 3, 2013, petitioner's counsel said he had contacted both Dr. Marcel Kinsbourne, a pediatric neurologist, and Dr. M. Anthony Verity, a pathologist, and sent Dr. Verity the autopsy slides, in the hope of obtaining expert reports from them. Petitioner's counsel was aware that Dr. Shane had been accused of criminal behavior in another forum.²

During a telephonic status conference on February 20, 2013, petitioner's counsel said that Dr. Verity told him he was too busy to proceed. Petitioner's counsel said he was looking for another pathologist, but if he could not find one, he would move for a ruling on the record.

During a telephonic status conference on April 9, 2013, petitioner's counsel said that he had a neurologic expert, Dr. Victor Hogen, and expected his report in four days.

² Dr. Shane was charged with conspiracy to create phony wills by acting as a witness to the supposed signing of wills by two people who were already dead at the time of the "signing." <http://abclocal.go.com/wpvi/story?section=news/local&id=6414875> (last visited July 19, 2013). As part of a plea agreement by the instigator of the phony wills, criminal charges against Dr. Shane and a co-conspirator were withdrawn. <http://articles.mcall.com/2012-08-14/news/mc-northampton-john-karoly-will-dispute-20120814> (last visited July 19, 2013).

During a telephonic status conference on May 7, 2013, petitioner's counsel said that Dr. Victor Hogen could not support petitioner's allegations. He said that Dr. Verity could not support petitioner's allegations either.

During a status conference on July 10, 2013, petitioner's counsel said that he had spoken to Dr. Kinsbourne and Dr. Verity both of whom believed there was not enough brain edema to cause death. Petitioner's counsel had Dr. Verity's letter.

On July 10, 2013, petitioner moved for a ruling on the record. Counsel stated in the motion, "In a status conference conducted on July 10, 2013, petitioner's counsel advised the court that his efforts to find an expert to support the client's position failed (see Ex. A)." Pet. Mot. at 2, ¶ 4. Exhibit A attached to petitioner's motion consists of a letter from Dr. M. Anthony Verity, Emeritus Professor of Pathology and Laboratory Medicine, University of California, Los Angeles, remarking on his review of Erasmo's brain tissue, consisting of six slides out of a total of 15 glass slides. Pet. Ex. A, at 1. These sections did not reveal any abnormality suggestive of acute disseminated encephalitis or inflammation. Although Erasmo's brain weighed more than the average for infants of similar length and age, Dr. Verity stated the increase was within the range of standard references. *Id.* Dr. Verity disagreed with petitioner's former expert pathologist, Dr. John Shane, who claimed the slides showed a vaccine-related neuropathic process. Dr. Verity stated there were virtually no defined neuropathic changes in Erasmo's brain that would be consistent with vaccine injury. *Id.* at 2. Moreover, there was no evidence of Purkinje cell degeneration, as Dr. Shane wrote that he had seen. *Id.* Dr. Verity concludes, "the neuropathology evaluation does not support many of the claims made by Dr. Shane. A minor component of cerebral edema may be present but confounded by the component of fixation artifact. No other brain changes lend any support for an underlying 'vaccine-mediated neuropathic process.'" *Id.*

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In *Althen*, the Federal Circuit quoted its opinion in *Grant v. Secretary of Health and Human Services*, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[.]" the logical sequence being supported by "reputable medical or scientific explanation[.]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

Without more, “evidence showing an absence of other causes does not meet petitioners’ affirmative duty to show actual or legal causation.” Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioner must show not only that but for Erasmo’s vaccinations, Erasmo would not have died, but also that the vaccines were a substantial factor in causing his death. Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Vaccine Act does not permit the undersigned to rule in favor of petitioner based solely on her allegations unsupported by medical records or credible medical opinion. 42 U.S.C. § 300aa-13(a)(1). Dr. Shane’s opinion is completely negated not only by respondent’s two experts, Dr. Vargas and Dr. Lidov, but also by petitioner’s second expert pathologist, Dr. Verity. All agree that the autopsy slides do not show brain edema or neuropathic degeneration, which is the basis for Dr. Shane’s opinion about vaccine causation. In addition, the pathologist who did the autopsy, Dr. Farley, did not find any brain edema or abnormality that would indicate any cause of death other than the possible overlying or smothering of Erasmo as he slept with three siblings in a twin bed that contained blankets and pillows. The Federal Circuit has emphasized that special masters are to consider seriously the opinions of treating physicians. Broekelschen v. Sec’y of HHS, 618 F.3d 1339, 1347 (Fed. Cir. 2010); Andreu v. Sec’y of HHS, 569 F.3d 1367, 1375 (Fed. Cir. 2009); Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1326 (Fed. Cir. 2006). Even though Dr. Farley was not a “treating” doctor, she was acting as a pathologist before this litigation ever began by performing an autopsy to determine the cause of Erasmo’s death. She could find nothing abnormal in his tissues to lead to a conclusion other than SIDS.

Petitioner has not satisfied the three prongs of Althen in that she has not presented a credible medical theory explaining how these vaccinations could cause death or that there is a logical sequence of cause and effect showing that these vaccinations did cause Erasmo’s death. She has failed to make a prima facie case. This is a tragic case and the undersigned expresses sympathy for petitioner’s loss. However, the weight of the evidence from Dr. Verity (for petitioner), Dr. Vargas (for respondent), Dr. Lidov (for respondent), and Dr. Farley (as part of her responsibilities as the pathologist performing the autopsy) leads to the conclusion that Erasmo’s vaccines had nothing to do with his demise.

Petitioner’s motion for a ruling on the record is **GRANTED**. This petition is hereby **DISMISSED**.

CONCLUSION

Petitioner’s petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment herewith.³

³ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.

IT IS SO ORDERED.

July 26, 2013
DATE

s/Laura D. Millman
Laura D. Millman
Special Master